

### **REMARKS/ARGUMENTS**

Reconsideration is respectfully requested in view of the amendments and remarks presented herein.

#### **Status of the Claims**

Claims 1-28 are pending in the application. Claims 11-15, 18, and 21-28 have been previously withdrawn from consideration by the Examiner as drawn to non-elected subject matter.

#### **Discussion of the Amendment to the Claims**

The claims have been amended to more particularly point out and distinctly claim the subject matter of the present invention and not in acquiescence of any rejection. In particular, claim 1 has been amended to recite that film includes weakened sections which divide the film into segments that represent individual dosage units. Support for the amendment to claim 1 may be found in the application as originally filed at, for example, page 5, paragraph [0025]. No new matter has been added by way of the amendments to the claims.

#### **Response to the Rejection under 35 U.S.C. §103(a) in view of Cremer**

Claims 1-7, 16, 17, 19 and 20 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over U.S. Patent No. 6,655,112 to Cremer et al. (hereinafter "Cremer"). In particular, the Examiner has stated the following:

It is the position of the Examiner that the perforations of Cremer are equivalent to the "one or more weakened sections" of the present claims; the only distinction being that the perforations of Cremer occur within the packaging material. However, here again, the packaging material of Cremer has not been excluded based on the present claim language. Furthermore, note in particular that the claim language "which permit said dosage units to be detached from said film" indicates a future-intended use

or capability of the film, i.e., that it is detachable. Nowhere in the claims is the detachment of the dosage units required.

(Advisory Action, page 2).

Applicants respectfully traverse the rejection and request reconsideration in view of the remarks and amendments presented herein.

Applicants respectfully maintain that the rejection of claims 1-7, 16, 17, 19, and 20 under 35 U.S.C. §103(a) in view of Cremer is improper for the reasons of record. Moreover, as one of ordinary skill in the art would appreciate and contrary to the contention of the Examiner, the perforations of Cremer (which, as admitted by the Examiner are within the packaging material) are not the equivalent of the “one or more weakened sections” of the pending claims. Indeed, it is respectfully noted that the Examiner has provided no reasoning in support of this unsubstantiated allegation.

Nevertheless, to advance prosecution and not in acquiescence of the rejection, claims 1 and 11 have been amended. As amended, claims 1 and 11 require an edible film which includes weakened sections which divide the film into segments that represent individual dosage units. As such, amended claims 1 and 11 require the following:

- that the film itself includes weakened sections; and
- that the weakened sections divide the film into segments that represent individual dosage units.

In contrast, “the perforations of Cremer are within the packaging material,” as admitted by the Examiner, and not within the film itself. (Advisory Action, page 2). Specifically, the packaging unit of Cremer has “a perforation between the compartments in which the individual

dosage units are situated.” (Col. 4, lines 23-24, of Cremer). As such, Cremer discloses “single dosage units” which are separately sealed within separate compartments in keeping with Cremer’s purpose of providing for “the targeted removal of a single dosage unit by pressing it through the primary packaging unit.” (Col. 4, lines 15-16, and Col. 7, lines 14-16, of Cremer).

As Cremer requires perforations within the packaging material to allow for compartmentalized, individually packaged single dosage units, Cremer teaches away from film as recited in amended claims 1 and 11 which has weakened sections within the film itself. Indeed, there is no disclosure or suggestion in Cremer of film having weakened sections which divide the film into segments that represent individual dosage units.

Moreover, modification of the film of Cremer to include perforations within the film itself would contravene Cremer’s intent and purpose of providing individually packaged single dosage units and would change the principle of Cremer’s manufacturing process, which is designed to seal single dosage units into separate compartments. (See Col. 4, lines 21-28, and Col. 7, lines 14-16, of Cremer; see also MPEP §2143.01.V (internal citation omitted) (indicating that if a “proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification”) and MPEP 2143.01.VI (internal citation omitted) (indicating that if a proposed modification would change the principle of operation of the prior art invention being modified, then the teaching of the reference is not sufficient to render the claims *prima facie* obvious).

Thus, amended claims 1 and 11 are not obvious in view of Cremer.

Claims 2-7 all depend from amended claim 1. Accordingly, claims 2-7 are not obvious in view of Cremer for the same reasons discussed above with respect to amended claim 1. Indeed, there is no disclosure or suggestion in Cremer of the subject matter of claims 2-7.

Claims 16-17 and 19-20 all depend directly or indirectly from amended claim 11. Accordingly, claims 16-17 and 19-20 are not obvious in view of Cremer for the same reasons discussed above with respect to claim 11. Indeed, there is no disclosure or suggestion in Cremer of the subject matter of claims 16-17 and 19-20.

In view of the foregoing, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a) with regard to claims 1-7, 16, 17, 19, and 20 in view of Cremer.

**Response to the Rejection under 35 U.S.C. §103(a) in view of Chen**

Claims 1-10, 16, 17, 19 and 20 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over WO 00/42992 to Chen et al. (hereinafter “Chen”). In the Advisory Action, the Examiner has alleged that Chen teaches “a dosage unit comprising a perforated film strip.” (Advisory Action, page 2). Moreover, the Examiner has further stated that the Applicant has not shown that “the perforated film strips of Chen are not equivalent to films instantly claimed.” (*Id.*). Applicants respectfully traverse the rejection and request reconsideration in view of the amendments and remarks presented herein.

Applicants respectfully submit that the rejection of claims 1-10, 16, 17, 19, and 20 under 35 U.S.C. §103(a) in view of Chen is improper for the reasons of record. In particular, as previously noted on the record, “the perforated film strip 19” shown in Figure 3 of Chen is nothing more than a strip of film which has been cut into film units. As such, it is in no way the equivalent of a film which includes dosage units which are releasably joined by one or more

weakened sections, wherein the weakened sections permit the dosage units to be detached from the film.

Moreover, contrary to the contention of the Examiner, Applicants never argued that “the fact that the film can be ‘releasably joined’ signifies a use of the film, but the instant claim language does not necessarily require detachment of the film.” (Advisory Action, page 2). Rather, Applicants argued the following:

Contrary to the contention of the Examiner, the phrase “releasably joined...which permit said dosage units to be detached from said film” is not “a future-intended use limitation.” Rather, the feature of the dosage units being releasably joined by one or more weakened sections and the feature of the weakened sections permitting the dosage units to be detached from the film are characteristics of the film.

(Response dated July 12, 2010, page 5).

Nevertheless, to advance prosecution and not in acquiescence of the rejection, claims 1 and 11 have been amended. As amended, claims 1 and 11 require an edible film which includes weakened sections which divide the film into segments that represent individual dosage units. As such, amended claims 1 and 11 require the following:

- that the film itself includes weakened sections; and
- that the weakened sections divide the film into segments that represent individual dosage units.

In contrast, as noted above, “the perforated film strip 19” shown in Figure 3 of Chen is nothing more than a strip of film which has been cut into film units. As such, it is not a film

which includes weakened sections which divide the film into segments that represent individual dosage units.

Thus, amended claims 1 and 11 are not obvious in view of Chen.

Claims 2-10 all depend either directly or indirectly from amended claim 1. Accordingly, claims 2-10 are not obvious in view of Chen for the same reasons discussed above with respect to claim 1. Indeed, there is no disclosure or suggestion in Chen of the subject matter of claims 2-10.

Claims 16-17 and 19-20 all depend directly or indirectly from amended claim 11. Accordingly, claims 16-17 and 19-20 are not obvious in view of Chen for the same reasons discussed above with respect to claim 11. Indeed, there is no disclosure or suggestion in Chen of the subject matter of claims 16-17 and 19-20.

In view of the foregoing, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a) with regard to claims 1-10, 16, 17, 19, and 20 in view of Chen.

#### **Additional Remarks**

As claims 11-15 and 18 are within elected Group I and are generic with respect to the previously elected species, Applicants respectfully request that those claims be considered and that their status as “withdrawn” be withdrawn.<sup>1</sup>

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<sup>1</sup> Applicants wish to clarify that claims 16-17 and 19-20 all depend either directly or indirectly from claim 11 and not from claim 1, as was previously indicated.

Application No. 10/521,823  
Amendment and Response Accompanying a RCE dated August 11, 2010  
Further Reply to Office Action of May 11, 2010, and  
Reply to Advisory Action of August 5, 2010  
Docket No. 1199-13 PCT/US/RCE  
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**Concluding Remarks**

This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned at the telephone number given below.

No fees are deemed due. However, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this submission or any future submission pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



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